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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Miller et al.)
Serial No.: 09/258,947) Examiner: G. Ewoldt
Filed: March 1, 1999) Art Unit: 1644
For: MIMOTOPES AND ANTI-MIMOTOPES)
OF HUMAN PLATELET)
GLYCOPROTEIN IB/IX)

REPLY BRIEF

Assistant Commissioner for Patents
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MS AF

Sir:

I. Issues

A. The Examiner has argued that the claims are not described in the specification in a manner which meets the requirements for written description. For the first time, however, in the Examiner's Answer, the Examiner has argued that the specification fails to describe the structural features of the peptides which would render them able to inhibit ristocetin induced aggregation of platelets (Examiner's Answer, page 3, 6th paragraph).

As Applicant's have consistently argued, the specification as filed satisfies the written description requirement for the claims. In particular, page 22, lines 3-12 of the application as filed fully describes an isolated molecule capable of binding to an isolated peptide which comprises an amino acid sequence as shown in SEQ ID No:174. Further, the specification on page 22, lines 6-11 indicates that the isolated molecules inhibit ristocetin induced aggregation of platelets and has a three dimensional structure complementary to the three dimensional structure of the isolated peptide. Peptides of from 5 to 20 or 20-40 amino acids in length are described on page 14, lines 7-16. Further, a large number of species are listed that define the claimed genus (see specification, page 17, line 23-page 18,

line 15). Each of the listed species of peptides is defined as meeting the limitations of the claims. Claim 11 is fully described on page 24, line 33-page 25, line 18.

As stated previously by applicants, in order to meet the written description requirements, an actual reduction to practice is not required. Applicants have included an adequate written description of the invention showing sufficient, relevant, identifying characteristics that would have indicated to a person of ordinary skill in the art that applicants had possession of peptides which bind to SEQ ID NO:174, are 5-20 or 20-40 amino acid residues in length, inhibit ristocetin induced aggregation of platelets and have a three-dimensional structure complementary to the three dimensional structure of the peptide as shown in SEQ ID NO:174. As such, the written description requirements are fulfilled (Manual of Patent Examining Procedure (MPEP) 2163). Accordingly, the rejection of claims 9 and 11 for lack of written description is improper and should be withdrawn.

B. It is the Examiner's position that none of the listed species of antimimotopes have been shown to meet all of the limitations of the claims and, therefore, the claims are rejected for lack of enablement.

Applicants submit that this is the improper standard in determining enablement. The present application, as filed, adequately describes how to make and use the present invention. In particular, the specification describes a method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claims without requiring undue experimentation. Experimentation is permissible, if routine or if the specification provides a reasonable amount of guidance (MPEP 2164.05).

In particular, the specification, as filed, identifies numerous anti-mimotope sequences (for example, page 17, line 22 to page 23, line 15) which bind to the isolated peptide (the mimotope). An example of the methodology of

identifying peptides which bind to the mimotope sequence is provided at page 29, line 33 et seq. A description of the synthesis of a peptide is shown at page 39, line 6 et seq. Furthermore, the claims, in addition to being limited in regard to the particular mimotope sequence, are also limited to those peptides that inhibit ristocetin induced aggregation of platelets. The identification of such peptides which have this desired functional property can be routinely done using, for example, the methodology disclosed in the specification at page 38, line 13 through page 40, line 20.

The Examiner has argued that only one peptide is shown to inhibit ristocetin induced aggregation of platelets. However, as shown on page 42, line 28 to page 43, line 25, 57 unique sequences were determined which, when tested, demonstrated inhibitory activity above background level in a functional platelet assay.

Accordingly, the rejection of claims 9 and 11 for lack of enablement is improper and should be withdrawn.

For the above reasons, applicant maintains that the claims define patentable subject matter and accordingly the claims should be allowed.

Respectfully submitted,

July 6, 2004
Date

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